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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/310,685 05/04/99 LAMB

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020999  
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HM22/1023

EXAMINER

DECLoux, A

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

9-1  
1-6:30

# Office Action Summary

Application No.  
09/310,685

Applicant(s)

Lamb

Examiner  
DeCloux, Amy

Art Unit  
1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Aug 1, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 7-25 and 27-41 is/are pending in the application

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☒ Claims 7-25 and 27-41 are subject to restriction and/or election requirements

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☒ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20) ☐ Other:

### DETAILED ACTION

Note: The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Amy DeCloux, Group Art Unit 1644, Group 1640, Technology Center 1600.

1. Applicant's amendment, mailed 7-27-01 in Paper No. 12, is acknowledged.
2. However, upon review of the previous restriction requirement mailed 4-27-01 by the former examiner, shows that Group I (Claims 27-32) contains more than one invention. The method recited in claim 32 which is a method of modulating expression of a functional notch protein or notch signaling pathways involving a notch ligand is distinct from the methods recited by claims 27-31 which recite a method of treatment comprising administering a notch ligand or fragments or derivatives or analogues thereof.

Because of the patentably distinct methods included in group I, a new restriction of the instant is imposed. However, in view of applicant's arguments in said amendment, the species requirement of Group I presented in the previous restriction requirement mailed 4-27-01, has been withdrawn.

4. A restriction is required under 35 USC 121 and 372 between one of the following groups:

I. Claims 27-31 and 33-42, drawn to a method of treatment comprising administering a notch ligand or fragments or derivatives or analogues thereof, classified in class 514, subclass 2,

II. Claims 7-12, drawn to a method of tolerizing T cells to an antigen or allergen using notch ligand antigen presenting cells, classified in class 435, subclass 373,

III. Claims 13-17, drawn to notch ligand conjugates, classified in class 530, subclass 350,

IV. Claim 18, drawn to a kit comprising notch proteins or family members, classified in class 435, subclass 7.24,

V. Claim 19, drawn to an assay determining the effect of a compound on a ligand binding to notch, classified in class 436, subclass 501,

VI. Claim 20, drawn to a ligand capable of binding delta or serate, classified in class 530, subclass 350,

VII. Claim 21, drawn to an assay for free notch, delta or serate, classified in class 424, subclass 9.1,

VIII. Claim 22, drawn to an assay for determining a compound's effect on notch protein or notch ligand expression or processing, classified in class 435, subclass 6,

IX. Claim 23, drawn to compounds which affect notch or notch ligand expression, classified in class 536, subclass 24.5,

X. Claims 24 and 25, drawn to a compound which down regulates Delta or serrate expression, classified in class 536, subclass 24.5,

XI. Claim 32, drawn to a method of modulating expression of a functional notch protein or notch signaling pathways involving a notch ligand, classified in class 435, subclass 377.

5. The inventions listed as Groups I-V are distinct for the following reasons:

6. Groups III, IV, VI, IX and X are unique products. They differ with respect to their structures and physicochemical properties, and are therefore patentably distinct.

7. Groups I-II, V, VII-VIII and XI are unique methods. They differ with respect to process steps and endpoints to achieve different goals. Therefore, they are patentably distinct each from the other.

8. Groups III and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the notch ligand conjugates can be used as an antigen in a process for producing monoclonal antibodies.

9. Groups IV, VI, IX-X and II, V, VII-VIII and XI are unrelated products and methods and are therefore patentably distinct.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

matter, restriction for examination purposes as indicated is proper.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).


11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. a dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. a Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers **other than elections** related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.  
Patent Examiner  
Group 1640, Technology Center 1600  
October 19, 2001

  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT-182 /644